

Serial No.: 10/657,075

REMARKS

Claims 41-60 are pending in the present application, wherein claims 58-60 are newly added claims. Support for claims 58 can be found, *inter alia*, on page 18 line 21 through page 19 line 3; page 15 lines 13-18; and page 22 lines 16- 17, of the present specification. Support for claim 59 can be found, *inter alia*, on page 14, lines 14-16, of the present specification. Support for claim 60 can be found in parent claim 52. Accordingly, no new matter has been introduced by the above-amendments.

Rejection over JP 06-056700 in view of Patel et al. and Wear et al.

Claims 41-57 have been rejected under 35 U.S.C. § 103(a) as allegedly being obvious over JP 06-056700 (JP '700) in view of Patel et al., US 6,248,363, (Patel) and Wear et al., US 4,640,020, (Wear). This rejection is respectfully traversed. Specifically the Examiner has failed to establish a *prima facie* case of obviousness.

The presently claimed invention relates to the discovery of a process that surprisingly forms pharmaceutically acceptable spherical pellets. Specifically, independent claim 41 recites a process for making pharmaceutically acceptable spherical pellets that comprises, *inter alia*, combining, other than by spraying, a solvent with a pharmaceutically active agent and/or salt thereof and at least one pellet forming carrier to form a wet mixture. The wet mixture is then stirred, chopped or both to form spherical wet pellets. That the solvent can be combined without special control, e.g. without spraying, and yet mere stirring and/or chopping provides a spherical pellet is surprising. Indeed, Patel teaches in column 46, lines 31-35 that "[f]or granulation, a binder liquid is sprayed from via one or two binary nozzles located axially to the rotational movement of the powder bed. This operation results in rounding of the granules to

Serial No.: 10/657,075

approximately spherical pellets." Thus, when combining the solvent with the other ingredients, the solvent is sprayed in order to round the granules and form spherical pellets. This is a conventional prior art approach and does not teach or suggest combining the solvent without spraying as per the presently claimed invention.

The Examiner cites JP '700 as teaching the preparation of spherical pellets by adding medicine, crystalline cellulose, water and other components into an agitator/chopper. However, the Examiner does not allege that JP '700 teaches combining the solvent, such as water, without spraying. Indeed, JP '700 appears to teach restricting the flow of water during granulation in paragraph 21 by referring to its addition as 'by carrying out quantum dropping.'¹ Moreover, the point of JP '700 appears to be a formulation that allows fine (less than 400 μm) coated granules to be formed without cracking, chipping or powdering. It is the amount of crystalline cellulose that JP '700 finds important. The disclosure does not appear to teach any kind of new or different method of granulating and thus does not teach or suggest the process of the presently claimed invention.

It should be remembered that the operability of the presently claimed invention is surprising. As described on page 15 of the present specification, the initial stirring/chopping may form agglomerations that are too large, but that these agglomerations unexpectedly transform into high quality spherical pellets upon additional stirring/chopping optionally with the addition of more solvent. Such a startling discovery is not apparently taught in JP '700.

¹ JP '700 is a Japanese language document and no translation was provided with the Office Action. The undersigned obtained a rough "machine" translation which forms the basis of the descriptions and rough quotations contained herein. If the Examiner would like a copy of this machine translation, he is encouraged to contact the undersigned and a copy will be promptly provided.

Serial No.: 10/657,075

Patel likewise does not teach or suggest forming spherical pellets without spraying the solvent during granulation. To the contrary, Patel teaches away from the claimed process by requiring the use of spraying as mentioned above (and as more fully described in the Request for Reconsideration filed August 9, 2004).

Wear is relied upon to show that microwave energy is known for drying granules. But not even the examiner asserts that Wear teaches or suggests the formation of spherical pellets by stirring/chopping without spraying the solvent.

In view of the above, the Examiner has failed to establish a *prima facie* case of obviousness. Specifically, none of the applied prior art teaches or suggests applicants' claimed step (1) "wherein the solvent is not combined by spraying." In the absence of any suggestion of such a process step, the Examiner's rejection lacks the required motivation to properly render obvious the presently claimed subject matter. For this reason alone the rejection should be withdrawn.

But various dependent claims are even further removed from the teachings of the applied art and are thus more clearly patentable over the art. For example, the concept of dumping water in claim 43 and the short time limits expressed in claims 44 and 45 are nowhere found in the applied art. Only by improper hindsight reconstruction or unsupported allegation can the Examiner find such features to have been obvious. Similarly, claim 58 recites pellets having an average diameter from 0.5 to 2.0 mm. In contrast, JP '700 is specifically drawn to fine granules having a size of 80 to 400 μm (i.e. 0.08 to 0.4 mm). Indeed, JP '700 apparently seeks to solve a coating problem associated with such fine granules by controlling the composition. JP '700 does not suggest forming the larger spherical pellets of the claimed process, nor does it suggest the

Serial No.: 10/657,075

operability of its process in forming such larger pellets. Claim 59 recites that solvent is combined without a flow restraining device. Not only is such a feature not taught in the applied art, but in fact a restraining device is apparently taught in both JP '700 (quantum dropping) and Patel (spray nozzles). Thus claim 59 is further unobvious over the applied art.

In view of these and other distinctions, the formation of the presently claimed subject matter could not have been obvious within the meaning of 35 U.S.C. § 103. Therefore, reconsideration and withdrawal of this rejection are respectfully rejected.

Conclusion

In view of the above remarks, all claims define novel, patentable subject matter. Reconsideration of the rejection and allowance of the application are respectfully requested.

Should the Examiner have any questions regarding this application, he is encouraged to contact applicants' representative, Mark R. Buscher (Reg. No. 35,006) at telephone No. 703 753 5256.

Respectfully submitted,



Mark R. Buscher
Registration No. 35,006

P.O. Box 161
Catharpin, VA 20143